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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David K. Swanson

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EXAMINER

ROANE, AARON F

ART UNIT

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/727,096	Applicant(s) SWANSON, DAVID K.	
	Examiner AARON ROANE	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10-12,28-35,37-40,43,44,46,47 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,11,28,30-35,37-40,43,44,46,47 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/11/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case claim 44 recites “the tube comprises a flexible tube and depends on claim 43 which already recites a flexible tube.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 10, 11, 40, 54 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Staver (USPN 4,469,105).

Regarding claims 7 and 11, Staver disclose a surgical apparatus, comprising: a tube (18) defining a central axis and having a proximal end and a distal end; a suction device (10) formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue, the suction device extending from the tube distal end such that the peripheral sealing surface is located distally of the tube distal end and extends outwardly beyond an outer surface of the tube distal end such that suction device across the peripheral sealing surface is wider than the tube distal end; and a tissue stimulation element in the form of an electrode (13) that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device; wherein the suction device does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue, see col. 3, line 41 through col. 6, line 25 and figures 1-7.

Regarding claim 10, Staver further disclose that the suction device (10) is substantially cup-shaped, see figures 1-7.

Regarding claims 40, 54 and 57, Staver discloses the claimed invention, see col. 3, line 41 through col. 6, line 25 and figures 1-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staver (USPN 4,469,105) as applied to claim 7 above, and further in view of Lundback (USPN 4,646,747).

Regarding claims 8 and 47, Staver discloses the claimed invention except for the flexible tube and/or a signal line that is connected to the tissue stimulation element and extends through the tube. Lundback discloses a surgical apparatus comprising a tube (8) defining an axis (inherent) and having a proximal region (with a proximal end) and a distal region (with a distal end); a cup-shaped suction device (1-3 collectively) associated with the distal region of the tube and defining a surface (surface defined by 4), wherein the cup-shaped suction device is made from a flexible material (flexible bending portions of 2), a tissue stimulation electrode (the tissue contacting side of 30) on the suction device distal surface; a source of stimulation energy ("electrical power source not shown" see col. 3, lines 3-12) connected to the stimulation electrode; and a suction source (see col. 3, lines 26-29), see col. 3 and 4 and figures 1-4. Lundback teaches providing an elongate flexible tube (8) in order to provide connection of the cup-shaped suction device with negative

pressure via a vacuum source located remotely, see col. 3-5 and figures 1-4. Lundback further teaches providing the device with a signal line that is connected to the tissue stimulation element and extends through the tube in order to provide electrical communication. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Staver, as taught by Lundback, to provide an elongate flexible tube in order to provide connection of the cup-shaped suction device with negative pressure via a vacuum source located remotely, and still further taught by Lundback, to provide the device with a signal line that is connected to the tissue stimulation element and extends through the tube in order to provide electrical communication.

Claim 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staver (USPN 4,469,105) as applied to claim 7 above.

Regarding claim 37 and 38, Staver discloses the claimed invention except for the stimulation element defining a perimeter of about 1.5 mm to 3 mm and a thickness of about 0.01 mm. The examiner takes official notice of the perimeter as it is trivial to provide the annular electrically conductive member 13 (electrode) of Staver with perimeter of about 1.5 mm to 3 mm corresponding to the cross-sectional area of 13 and a thickness (skin depths) of about 0.01 mm in order to electrode with its full functioning capabilities.

Claims 28, 30, 43, 44, 46, 55, 56, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staver (USPN 4,469,105) in view of Lundback (USPN 4,646,747).

Regarding claims 28, 43 and 44, Staver disclose a surgical apparatus, comprising: a tube (18) defining a central axis and having a proximal end and a distal end; a suction device (10) formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue, the suction device extending from the tube distal end such that the peripheral sealing surface is located distally of the tube distal end and extends outwardly beyond an outer surface of the tube distal end such that suction device across the peripheral sealing surface is wider than the tube distal end; and a tissue stimulation element in the form of an electrode (13) that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device; wherein the suction device does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue, see col. 3, line 41 through col. 6, line 25 and figures 1-7. Staver fails to disclose the flexible tube. Lundback discloses a surgical apparatus comprising a tube (8) defining an axis (inherent) and having a proximal region (with a proximal end) and a distal region (with a distal end); a cup-shaped suction device (1-3 collectively) associated with the distal region of the tube and defining a surface (surface defined by 4), wherein the cup-shaped suction device is made from a flexible material (flexible bending portions of 2), a

tissue stimulation electrode (the tissue contacting side of 30) on the suction device distal surface; a source of stimulation energy ("electrical power source not shown" see col. 3, lines 3-12) connected to the stimulation electrode; and a suction source (see col. 3, lines 26-29), see col. 3 and 4 and figures 1-4. Lundback teaches providing an elongate flexible tube (8) in order to provide connection of the cup-shaped suction device with negative pressure via a vacuum source located remotely, see col. 3-5 and figures 1-4. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Staver, as taught by Lundback, to provide an elongate flexible tube in order to provide connection of the cup-shaped suction device with negative pressure via a vacuum source located remotely.

Regarding claim 30, Staver in view of Lundback disclose the claimed invention.

Regarding claim 46, Staver further disclose that the suction device (10) is substantially cup-shaped, see figures 1-7.

Regarding claims 55, 56, 58 and 59, Staver in view of Lundback disclose the claimed invention.

Claims 31-33 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staver (USPN 4,469,105) in view of Lundback (USPN 4,646,747) as applied to claim 28 above.

Regarding claims 31-33 and 39, Staver in view of Lundback disclose the claimed invention except for the stimulation element defining a perimeter of about 1.5 mm to 3 mm, a thickness of about 0.01 mm and a diameter of about 0.5 mm to 1.0 mm. The examiner takes official notice of the perimeter as it is trivial to provide the annular electrically conductive member 13 (electrode) of Staver with perimeter of about 1.5 mm to 3 mm corresponding to the cross-sectional area of 13 and a thickness (skin depths) of about 0.01 mm in order to electrode with its full functioning capabilities. It should be further noted that a circular perimeter of 1.5 mm to 3 mm yields a diameter of about 0.5 mm to 1 mm.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staver (USPN 4,469,105) in view of Lundback (USPN 4,646,747) as applied to claim 28 above, and further in view of Colliou et al. (US 7,020,531).

Regarding claims 34 and 35, Staver in view of Lundback disclose the claimed invention except for explicitly reciting that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10 mA and two stimulation pulses per second. Colliou et al. disclose a stimulating suction electrode device and teach providing the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μ sec to 20 msec in order to provide electrical stimulation, see col. 23, line 46 through col. 24, line 6 and figures 16A and 16B. Therefore at the time of the invention it

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would have been obvious to one of ordinary skill in the art to modify the invention of Staver in view of Lundback, as taught by Colliou et al., to provide the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μ sec to 20 msec in order to provide electrical stimulation to tissue.

Response to Arguments

Applicant's arguments with respect to claims 7, 8, 10, 11, 28, 30-35, 37-40, 43, 44, 46, 47 and 54-59 have been considered but are moot in view of the new ground(s) of rejection. Due to the newly recited subject matter of the electrode and the flexible distal peripheral sealing surface Staver was used individually or in combination with the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Friday 5:30AM-3PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AARON ROANE/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739